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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/471,523 12/23/99 VAN BREEMEN

R 21726/90386

EXAMINER

HM12/0829

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PRASTHOFFER, T

ART UNIT

PAPER NUMBER

1627

DATE MAILED:

08/29/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

## Office Action Summary

Application No.

09/471,523

Applicant(s)

BOLTON ET AL.

Examiner

Thomas W Prasthofer

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \*   c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

## **Detailed Action**

### **Change of Examiner**

The examiner of this application has changed from Barba Koroma to Thomas Prasthofer.

### **Status of the Application**

Receipt is acknowledged of an amendment and a response to an office action on June 5, 2001 in Paper No. 9.

### **Status of the Claims**

Claims 1-12 are pending in the present application and are subject to restriction and election of species requirements. All of the rejections made in the office action mailed February 5, 2001 are withdrawn. The examiner notes that an election of species requirement was mailed November 3, 2001 and no response to the election of species requirement has been received. In order to facilitate a thorough search of the prior art, restriction and election of species requirements are set forth below. The examiner regrets the inconvenience that this may cause applicant and will work with applicant to provide compact prosecution of this application.

### **Restriction**

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10 and 12, drawn to a method for determining whether a compound from a sample has predetermined characteristics, classified in numerous classes and subclasses, depending on the compositions of biological material, compound

in a sample, method of analysis of secondary solution, and reaction between a compound and biological material.

- II. Claim 11, drawn to a kit for analyzing compounds in a sample, classified in numerous classes and subclasses, depending on the compositions of biological material, test solution, and standard solutions with predetermined characteristics.

The inventions are distinct, each from the other because:

2. Inventions I and II are different and patentably distinct inventions because Invention I is a method for determining whether a compound from a sample has predetermined characteristics and Invention II is a kit that is not specifically adapted for use with the method of Invention I. The kit of Invention II comprises “a first solution containing a biological material, a buffer, a test solution, and a set of standard solutions with predetermined characteristics.” The components of such a kit are not limited to being used for the method of Invention I which includes continuous flow of supportive solutions, production of metabolites or assessing permeability and bioavailability. The kit of Invention II could be used, for example in the production and purification of a product from the batch fermentation of a recombinant bacterium.
3. Because these inventions are distinct for the reasons given above and
  - a. have acquired a separate status in the art as shown by their different classification ;
  - b. have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
  - c. have divergent subject matter, restriction for examination purposes as indicated is proper.
4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under CFR 1.17(h).

### **Election of Species**

6. This application contains claims directed to patentably distinct species of the claimed invention. If applicant elects Invention I, applicant is required to elect species for each of the following groups A-C.

A. species of biological material (e.g. protein, peptide, oligonucleotide, oligosaccharide, microsome, cell, tissue, DNA or RNA),

B. species of sample compound (e.g. natural product, drug, xenobiotic compound, endogenous compound, or combinatorial library. The species must clearly identify what type of compounds are in a mixture or library such as protein, DNA, RNA, drug, natural product etc...), AND,

C. species of predetermined characteristic (e.g. production of or lack of production of particular metabolites, permeability through a particular barrier such as a cell membrane or blood-brain barrier, or bioavailability),


7. The species are distinct, each from the other, because A&B) the compounds have different chemical structures with different chemical, physical, biochemical, pharmacological, and/or pharmaceutical properties and C) the different characteristic require different methods of determination that are specially adapted for the different characteristics and the methods of determination require different apparatus, conditions, reagents, and/or starting materials and produce different results. Therefore, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

8. Applicant is required under U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally to be allowable.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after election, applicant must indicate which are readable upon the elected species.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Thomas Prasthofer** at telephone number **(703) 308-4548**. The examiner can normally be reached on Monday, Tuesday, Friday, and Saturday 8:00-6:30.
11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.
12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Thomas Prasthofer, Ph.D.

August 27, 2001

  
**DR. JYOTHSNA VENKAT PH.D**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**